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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/362,394	07/28/1999	CHONG-JIN OON	56972/JPW/AK	6815

7590 11/30/2001

JOHN P WHITE ESQ
COOPER & DUNHAM LLP
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/30/2001

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/362,394

Applicant(s)

OON ET AL.

Examiner

Donna C. Wortman, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 17 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claims 1-18 were cancelled and new claims 19-68 were added in Paper No. 12 submitted 9/17/01. Claims 19-68 are presently under examination.

As a result of the amendment to the specification and the new claims presented in Paper No. 12, this application is no longer in compliance with the sequence rules. In particular, sequences embedded in the text of new paragraphs presented in the amendment (e.g., at page 9 and page 14) and in new claims 20, 21, 26, 29, 30, 35, 37, 39, 41, 43, 46, 47, 52, 53, 54, 58, 59, 64, 65, and 66 are not accompanied by the appropriate SEQ ID NO's as is required by 37 CFR 1.821(d). Applicant must supply the SEQ ID NO's in any response to this action.

Claims 19-41 are drawn to oligonucleotides; claims 42 and 43 are drawn to an oligonucleotide composition; claims 44-68 are drawn to methods for identifying hepatitis B viral nucleic acid sequences.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43, 53, 54, 65, and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 43, 53, 54, 65, and 66 are indefinite in reciting "has the sequence ...". It remains unclear whether Applicant intends "has" to represent open language, equivalent to "comprising," or closed language, equivalent to "consisting of." In the absence of amendment or clarification of what Applicant intends to claim, and

consistent with the practice of giving claims their broadest reasonable interpretation, the recitation of "has" has been interpreted as open language.

Claims 46-50, and 52, and claims 58-62, and 64 are indefinite in reciting "the oligonucleotide" without clear antecedent in independent claims 44 and 57, respectively. Claims 44 and 57 each recite "oligonucleotide" more than once, making it unclear which oligonucleotide is being claimed in the dependent claims.

Claims 19-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/40193 to Stuyver et al., of record, essentially for reasons of record in rejecting claims 1-18 in the previous Office action.

Applicant has argued that the cited reference at most describes PCR amplification of samples which may then be screened using labeled probes and points to examples 1 and 2 on pages 33 and 34. Applicant argues that the claimed invention differs in that it relates to the labeling of PCR amplified viral nucleic acids by using labeled PCR primers, where the reference uses labeled probes; that the claimed invention relates to immobilized probes, while the reference suggests using mobile probes; that the claims recite specific oligonucleotide sequences with particular lengths that are not suggested in the cited reference; that the claims recite particular labels, *viz.* Texas red and 6-FAM, not disclosed in the cited reference.

These arguments have been considered but not found persuasive. Stuyver et al. disclose labeled primers, labeled target DNA, and immobilized probes (see e.g., page 13, lines 8-22; page 16, lines 5-20). Further, none of the instant claims are limited to specific length oligonucleotides; even the claims that recite a specific sequence recite

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open language, either "comprising" or "has" that allows for longer oligonucleotides.

While Stuyver et al. does not specifically name Texas red and 6-FAM, it is noted that not all the instant claims are limited by the recitation of any specific label. Even for claims limited to the labels Texas red and/or 6-FAM, in the absence of persuasive argument or evidence to the contrary, any label of choice is deemed to be obvious over the teaching of Stuyver et al. to label the oligonucleotides to be used in the disclosed assays.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is

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703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:30-5:00 and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
November 29, 2001